

--55. (new) The composition according to claim 42, wherein the composition is in a form selected from the group consisting of a nutrition supplement, a total nutrition and a clinical nutrition.--

REMARKS

The application has been amended so as to place it in condition for allowance at the time of the next Official Action.

At the outset, applicants wish to thank Primary Examiner Hendricks for the courtesies extended during the personal interview held on March 27, 2003 with the undersigned agent. The Primary Examiner's careful attention to the application on that occasion is sincerely appreciated.

Claims 14-55 are present in the application.

Claim 14 has been amended.

New claims 27-55 have been inserted.

Claims 14-26 were rejected under 35 USC §102(b) as being anticipated by BROWN et al. (WO 97/34615). Claims 14-26 were also rejected under 35 USC §102(e) as being anticipated by CAVADINI et al. 5,968,569. Applicants respectfully traverse these rejections.

BROWN et al. describe a probiotic composition for enhancing the microbial colonization in the gastro-intestinal tract. The probiotic composition comprises the combination of a probiotic microorganism, a resistant starch, and an oligosaccharide. The probiotic microorganism is either a yeast

or a bacteria or a combination of the two which is present at a concentration range of 10^3 to 10^{13} cell per day (page 3, lines 22-23) or stated otherwise which is administered at a consumption rate of about 0.1 to 10 g per kg body weight (page 3, line 26). The oligosaccharide is present in an amount of 0.01% to 10% by weight (page 4, line 8).

CAVADINI et al. describe a dried food product comprising a gelatinized starch matrix which includes a coating or filling containing a probiotic microorganism. The probiotic microorganism can be a yeast, a bacteria or a combination of the two which is present in an amount of 10^4 to 10^{10} cells of probiotic microorganism per gram of the dried cereal product (column 6, lines 9-10). A source of soluble fiber may also be added to the product, which list includes, among others, inulin as well as fructo-oligosaccharides, the source of soluble fiber being present in a maximum amount of 20% by weight (column 4, line 7).

Claim 14 has been amended to recite "40-80 weight % of one or more oligosaccharides". Basis for the amendment to claim 14 is found at page 5, line 25 of the specification.

The high level of oligosaccharide is necessary to the survival of the probiotic to the passage in the GI tract. The high level of oligosaccharide is preferably directly in the neighborhood of the probiotics, thereby protecting the probiotics

and enhancing their survival by providing nutrition for the probiotics during their passage in the GI tract.

Neither BROWN et al. nor CAVADINI et al. describe such high levels of oligosaccharide. Further, there is no teaching in BROWN et al. or CAVADINI et al. that a high level of oligosaccharide would lead one of ordinary skill in the art to an expectation of success with regard to the performance of the compositions. BROWN et al. describe oligosaccharides at 1% whereas CAVADINI et al. describe a maximum of 20% but do not exemplify any soluble source of fibers, let alone oligosaccharides.

In view of the above amendment and remarks, applicants respectfully submit that claims 14-26 are neither anticipated by nor would have been obvious to one of ordinary skill in the art in view of BROWN et al. or CAVADINI et al.

New dependent claim 28 incorporates the subject matter of claim 14 and further recites "the amount of the at least one yeast strain being 0.5-5 g".

Basis for this amendment is found on page 4, line 27 of the specification. Although this refers to dead *Saccharomyces cerevisiae*, it is believed that, reading the application as a whole, this range can also be applicable to yeast in general. The reasoning behind this is taken from the paragraph on page 4, lines 11-13 which provides that the yeast "can be alive or dead. Both dead and live yeast contains a high content of manno-

proteins, which are able to prevent the adhesion of bacteria to the intestinal wall to a large extent." Thus, reading this paragraph, it then becomes clear that the level given for dead yeast thereafter represents the amount of yeast necessary to provide the high content of mannoproteins.

New dependent claims 29-40 correspond to dependent claims 15-26.

Such high levels of yeast in claims 28-40 will ensure that a sufficient amount of mannoproteins reaches the colon as part of it is partly degraded by the GI tract enzymes.

BROWN et al. fail to describe specific levels of yeast.

CAVADINI et al. describe and exemplify the combination of yeast and bacteria (Examples 6 and 7). However, the amount of exemplified product to be consumed to consume at least 0.5 g of yeast is 3125 g for Example 6 and 82304 g for Example 7. Such high quantities of product cannot realistically be consumed. Accordingly, applicants respectfully submit that CAVADINI et al. do not contemplate the use of 0.5-5 g of yeast.

The basis for the above calculations is taken from the value of 6.4×10^6 cfu yeast per gram (Example 6) and taking the assumption, in the absence of information on how much of these products are to be eaten to obtain a specific daily dose or how much yeast is to be consumed per day, that active dried yeast is known to contain 1.5×10^{10} to 2.5×10^{10} cfu/g (average of 2×10^{10} cfu/g is taken for the calculation). Therefore, to consume 0.5 g

of yeast, one should eat $(2 \times 10^{10} / 6.4 \times 10^6) = 3125$ g (Example 6) or $2 \times 10^{10} / 2.43 \times 10^6 = 82304$ g (Example 7).

Yeast, like the oligosaccharides, is needed in high levels to ensure survival of the probiotic to the passage in the GI tract. Neither BROWN et al. nor CAVADINI et al. recognize the importance of the presence of high levels of yeast.

In view of the above amendments and remarks, applicants respectfully submit that claims 28-40 are neither anticipated by nor would have been obvious to one of ordinary skill in the art in view of BROWN et al. or CAVADINI et al.

New independent claim 42 recites the limitation inserted into amended claim 14 and new claim 28.

New dependent claims 43-54 correspond to dependent claims 15-26.

New claims 42-54 are believed to be allowable for the same reasons set forth in regard to claims 14-26 and 28-40.

New dependent claims 27, 41 and 55 recite the form of the composition and are believed to be allowable for the same reasons set forth in regard to the other claims. Basis for claims 27, 41 and 55 is found at page 5, lines 9 and 10 of the specification.

In view of the above amendments and remarks, applicants believe that the present application is in condition for allowance and an early indication of the same is respectfully requested.

If the Examiner has any questions or requires clarification of any of the above points, the Examiner may contact the undersigned agent so that this application may continue to be expeditiously advanced.

Attached hereto is a marked-up version showing the changes made to the claims. The attached page is captioned "VERSION WITH MARKINGS TO SHOW CHANGES MADE."

Respectfully submitted,

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"VERSION WITH MARKINGS TO SHOW CHANGES MADE"

IN THE CLAIMS:

Claim 14 has been amended as follows:

--14. (amended) A composition for the prevention and/or treatment of disorders of the digestive tract, which comprises probiotics comprising at least one bacterial strain and at least one yeast strain and 40-80 weight % of one or more oligosaccharides that are non-digestible by humans, said composition being in dried form.--